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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,477	03/02/2004	Alan G. Harris	AL01350Q	2114

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,477	HARRIS ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-29-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Request for Continued Prosecution (RCE) filed December 29, 2005 following the First Action mailed June 29, 2005 is acknowledged and accepted. Claims 1-33 remain under consideration.

An Information Disclosure Statement filed December 29, 2005 is acknowledged and has been reviewed.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1984), *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982), *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 16, 26, 36, 37, 45 and 46 of copending Application No. 10/021,189. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the present application is encompassed in the co-pending application. The co-pending application merely recites the administration of "an antihistamine" without specifically reciting the antihistamine "loratadine".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the treatment and/or prevention of any cardiovascular disease comprising administering loratadine in combination with montelukast, optionally wherein the human is suffering from an allergic and/or inflammatory condition, rhinitis, dermatitis or urticaria. The specification provides no support for methods of treatment and/or prevention as recited.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation.

These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictabilitv of the art

The claimed invention relates to treatment and/or prevention of any cardiovascular disease comprising administering loratadine in combination with montelukast, optionally wherein the human is suffering from an allergic and/or inflammatory condition, rhinitis, dermatitis or urticaria.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the field of immunology.

Each particular allergic or cardiovascular disease has its own specific characteristics and etiology. The unpredictability observed with single agent therapy is compounded when a combination of agents is employed. The broad recitation "treating and/or preventing a cardiovascular disease" is inclusive of many conditions that

presently have no established successful therapies.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any cardiovascular disease.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples.

The quantity of experimentation necessary

Applicants have suggested lower immunoglobulin and/or eosinophil levels - compared to baseline levels - in patients treated in accordance with the present invention indicates improvement in the patient's condition and risk for cardiovascular disease on page 13 of the specification. A showing directed to lower immunoglobulin and/or eosinophil levels - compared to baseline levels - in patients treated in accordance with each aspect of the present invention would be given favorable consideration with respect to methods of treatment. Presently, guidance as to which particular cardiovascular disease is contemplated according to the recited limitations in the claims is absent. In particular, with respect to methods of prevention, the skilled artisan would expect the interaction of a particular combination of drugs in the treatment of a particular disease state to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. Absent

reasonable *a priori* expectations of success for using the particular combination of loratadine and montelukast to treat any particular cardiovascular disease, one skilled in the cardiology art would have to test extensively many disease states to discover which show efficacy. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belley et al., EP 0 480 717, particularly in view of Connor et al., U.S. Patent 5,177,259.

Belley teaches the administration of compounds of formula I that are leukotriene antagonists as anti-allergic and anti-inflammatory agents in the treatment or prevention of cardiovascular disorders. See page 7, line 35. Montelukast is a compound of formula 1. Seasonal or perennial allergic rhinitis, as required by instant claims 16-24, and atopic dermatitis or urticaria, as required by instant claims 25-33, would reasonably

be considered examples of allergic and inflammatory disorders. See page 12, lines 19-20, where an advantageous combination with an H_1 or H_2-receptor antagonist is disclosed. Loratadine is not specifically disclosed. However, Connor teaches the advantageous combination of loratadine in pharmaceutical compositions for treatment of cardiovascular diseases. See column 40, lines 8-11. Thus one skilled in the art would have been motivated to administer a pharmaceutical combination comprising loratadine with montelukast to treat or prevent a cardiovascular disease. Such would have been obvious because both compounds are known in the prior art for anti-inflammatory and anti-allergic effects. Belley teaches the administration of leukotriene antagonists for treating cardiovascular disorders. Connor teaches combining loratadine in a pharmaceutical composition for the treatment of cardiovascular disorders. The determination of optimal dosages of the drugs is a parameter well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

As a continuation, all claims are drawn to the same invention claimed prior to the Request for Continued Prosecution and could have been finally rejected on the grounds and art of record in the next Office Action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a First Action following the RCE. See MPEP 706.O7(b). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1. 136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1. 136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7PM. If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

February 3, 2006

Phyllis G. Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER